UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO MODIFY THE SCHEDULING ORDER OF THE COURT

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INTRODUCTION

It is understandable that the FDA does not want independent scientists to review the documents it relied upon to license Pfizer's vaccine given that it is not as effective as the FDA originally claimed, does not prevent transmission, does not prevent against certain emerging variants, can cause serious heart inflammation in younger individuals, and has numerous other undisputed safety issues.[1] However, the FDA's potential embarrassment over its decision to license this product must take a back seat to the transparency demanded by FOIA and the urgent need and interests of the American people to review that licensure data. The Court already recognized this unprecedented urgent need in its January 6th order directing the FDA to produce 55,000 pages per month.[2]

The FDA now insists it must delay its first 55,000-page production until May 1, 2022 – four months after the Court entered its order. However, the FDA's own papers seeking this delay make plain it can produce at a rate of 55,000 pages per month in February and March. The FDA affirms it has already "allocated the equivalent of nearly 11 full-time staff to this project" and that "a review speed of 50 documents per hour was within the normal range for document review in a complex matter" in private practice; and here the 50 document per hour rate would be faster since there is only a need to review for personally identifying information ("**PII**") for most pages. Hence, if the FDA's 11 full-time reviewers work only 7.5 hours per day and review 50 pages (not

[1] Reflecting the issues with this product, the FDA failed to send a representative to a federal court hearing in this matter on December 14th because of the "FDA's protocols" regarding COVID-19. Meaning, despite the FDA's claim the vaccine is "effective," the FDA is apparently still scared to send a representative to the hearing. Its actions speak volumes and cast serious doubt on its words.

[2] While the FDA asserts in its motion that Plaintiff "opposes the requested relief and stated that it will explain the reasons why in a written response to this Motion," Plaintiff clearly set forth within an email to FDA's counsel its reasoning for opposing the reduction in the monthly rate and the FDA chose to not respond and address any concern raised therein. *See* App000935-App000938.

documents) per hour, the FDA could review over 88,000 pages per month in February and March. That is more than sufficient to produce the 55,000 pages per month currently ordered for these two months.

Instead of complying with this Court's reasoned order, the FDA claims these 11 reviewers can only review a total of 10,000 pages per month. What the FDA does not say, and what basic math shows, is that a rate of 10,000 pages a month for 11 full-time reviewers amounts to **only 5 pages per hour**! This rate is made even more absurd because most of the pages the FDA will be reviewing during this period are repetitive data files that only require second level review to redact minimal amounts of PII that Pfizer may have left in the documents. FDA's reality defying claim and contemptuous approach to its production obligations should not be countenanced. (*Infra* § I.)

It is also apparent that the instant demand is just the start of a campaign to delay the production ordered by the Court. In this first salvo, the FDA is not really asking the Court. It is instead expressly *telling* the Court it does not intend to produce more than 10,000 pages per month for February and March, and despite claiming it is making "unprecedented" efforts, the FDA repeatedly tells the Court: "It is not possible to guarantee that FDA will be able to fully comply" with the 55,000-page production rate thereafter. (Dkt. No. 38 at APPX004, APPX008.) Americans must follow the law and the FDA, a multi-billion-dollar agency, should similarly be given no safe harbor from complying with the orders of this Court. (*Infra* § II.)

The FDA should also be held to what it attests. The FDA, with over 18,000 employees and an over $3 billion discretionary budget, repeatedly assures the Court that it is taking steps to "marshal every possible resource available to it," "acting with maximal urgency to assemble every possible resource available to it" and "putting every available resource at its disposal into its efforts to achieve compliance." (Dkt. No. 37 at 10, 3, 10.) The FDA also attests that over the coming

weeks, it will have 28.5 full-time people reviewing the documents. Working 7.5 hours per day for 20 business days per month, 28.5 people reviewing 50 pages per hour can review a total of approximately 213,750 pages per month. Putting aside that most of this production can be reviewed far faster than the rate of 50 pages per hour, Plaintiff asks that the FDA be held to its representations and be directed to produce at the rate of 180,000 pages per month starting in April. (*Infra* § III.)

The Court is, other than Congress, the only check on the FDA. In a free country, transparency is paramount, and the FDA has chosen to thwart transparency and the requirements of FOIA by anemically understaffing the office it maintains to respond to FOIA requests. It is akin to the boy that kills his parents and asks for sympathy for being an orphan. Decrying that this Court is now making it comply with the law – by actually producing documents in a timely manner – is ridiculous. It is also incredible for the FDA to claim that compliance here would harm its health policy objectives. Even if the FDA really does need to spend $4 to $5 million which, as shown below, is an absurd overestimate, that is an inconsequential amount of its overall $3.41 billion discretionary budget. Moreover, the issues with the Pfizer vaccine – including waning immunity, variants evading immunity, the failure to prevent transmission, myocarditis, and pericarditis – show that the FDA's priority should be to address this product before rushing off to engage in other activities. (*Infra* § IV.)

For these reasons, as explained below, the Court should refuse to reduce the rate of production in February and March and should increase the rate of production for April and thereafter to 180,000 pages per month consistent with the FDA employing 28.5 full-time reviewers in the coming weeks to conduct the review and the fact that most of the pages need only be reviewed for PII.

ARGUMENT

I. The FDA's Claim That it Cannot Produce 55,000 Pages on March 1st and March 31st is False

Plaintiff submitted the instant FOIA request in late August 2021 and filed this action in September 2021. (Dkt. No. 1.) Nearly four months later, on January 6, 2022, the Court rejected the FDA's patently unreasonable request to produce just 500 pages per month and instead ordered the FDA to produce 55,000 pages every 30 days starting on March 1, 2022. (Dkt. No. 35.) Now, the FDA wants to have that deadline pushed to May 1, 2022, which would be nearly four months after the Court entered its order and nine months after Plaintiff submitted its FOIA request. However, the FDA's excuses for seeking to further delay the production do not withstand even the most basic scrutiny.

Even more egregious, its excuses are plainly not tethered to the truth. The FDA is clearly dissembling when it claims it is taking steps to "marshal every possible resource available to it," that the "FDA is doing everything within its ability to comply with the January 6 Order," that it is "acting with maximal urgency to assemble every possible resource available to it," or that the "FDA is putting every available resource at its disposal into its efforts to achieve compliance with the Court's Order." (Dkt. No. 37 at 10, 2, 3, 10.) It requires suspending reality to accept that the FDA, with over 18,000 employees and its multi-billion-dollar discretionary budget, could not comply with the Court's deadlines if it were truly marshaling every possible resource available to it. If it was doing so, it could complete the entire production in even less than the originally requested 108 days.

After making the false claim that it is marshaling every possible resource, which it apparently defines as assigning "nearly 11 full-time staff to this project" (out of its over 18,000 employees), it then makes the outrageous claim to this Court that these nearly 11 full-time staff

can only produce 10,000 pages per month in February and March. Some simple math reveals just how absurd this claim is and how it stretches reason to accept that the FDA itself believes this claim. There are a total of 43 business days during this period, and assuming the 11 reviewers work 7.5 hours per day, 10,000 pages per month amounts to an average review pace of just **5 pages per hour!**

Bringing the absurdity of the FDA's position into even sharper focus is the straight-forward nature of this production. There is no dispute as to the universe of responsive documents. The FDA has never needed to conduct elaborate searches for documents or engage in a long collection process. The agency just needs to review the documents already in the Pfizer vaccine's biologics license file. The FDA does not need to review those documents for relevance because if a document is in the file, then it is relevant and responsive.

As for reviewing the unquestioned universe of documents, the FDA admits it needs to review these documents for only two exemptions: trade secrets and PII. That is it.

In its prior briefing, the FDA never contested that almost all the information requested is clinical trial data that does not contain trade secrets. Making its job even easier, the FDA has now asked Pfizer to confirm the portions of the requested documents that do not contain trade secrets by February 1, 2022. These non-trade secret documents almost certainly represent the vast majority of the production. This is obvious from the fact the FDA claims it will allocate 11 of the 15 contractors it is hiring to review "those records that do not require review for trade secret or confidential information." (Dkt. No. 37 at 3.)

As for the FDA's need to review for PII, the FDA never contested that Pfizer already redacted the PII before submitting its documents to the FDA (as it was required to do by FDA regulations). *See* 21 C.F.R. § 20.63(b). The FDA now just wants to do a second review, which is

fair enough. However, there is absolutely no reason why a trained reviewer can only review 5 pages per hour if all they are doing is a second level review for PII. Furthermore, for the new reviewers the FDA is hiring, beyond its 11 current experienced reviewers, training to review for PII cannot seriously take more than a few hours.

The production the FDA already delivered to Plaintiffs further evidences the absurdity of the FDA's claims concerning the complexity of the instant review. The index provided by the FDA for the Pfizer vaccine biologics file is 87 pages long. (App000939-App1026.) Out of those 87 pages, 68 pages contain just a long list of 1,035 case report forms ("**CRF**") files. Each CRF file contains only data from a clinical trial site. The FDA, based on Plaintiff's initial sampling request, produced 37 of the 1,035 listed CRF files. These 37 CRF files contained a total of 8,347 pages. Assuming this sampling is representative, the 1,035 CRF files in the total production will amount to around 250,000 pages, or more than half of the 450,000 pages that the FDA has indicated are responsive to the request at issue.

Taking a closer look at the sample 8,347 pages of CRF files produced to-date, the only redactions the FDA made were for a single type of PII data: date of birth and death. Nothing more. Moreover, all of the 8,347 pages are similar, most of them looking like one of the following two examples:

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811026 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:11

eCRF Audit Trail History

Demography		
1.	Subject ID	[10811026]
2.	Birth Date:	(b) (6)/1952
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

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Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[lymph node swelling]
4.	Start Date Time:	Jan/12/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 15:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

Claiming it will take a full hour to review 5 pages of the foregoing repetitive documents for only PII is absurd at best and, at worst, knowingly deceptive**.**

Included in Plaintiff's Appendix are the first 50 pages of each of the three CRF files produced to date, for a total of 150 combined pages. (App000785-App000934.) According to the FDA, a review of those pages should take approximately 30 hours. To test this claim, a paralegal at our firm replaced the redactions from these pages with made-up data. Attorney of record in this matter, Elizabeth Brehm, carefully reviewed this version of these 150 pages and redacted the relevant PII in just 14 minutes and 15 seconds. (App000781-App000782.) Ms. Brehm caught all three of the original redactions – which were birthdates. (*Id*.) This test shows that the FDA's time estimates are patently absurd. It also establishes that the instant request is far from evidence of the agency "doing everything within its ability to comply with the January 6 Order" as it claims, but rather is just another example of the agency trying to avoid or delay its FOIA obligations. (Dkt. No. 37 at 2.)

The Declaration of Douglas Weinfield, Associate Chief Counsel for Discovery within the Office of the Chief Counsel of the FDA, makes clear that during his "time in private practice, a review speed of 50 documents per hour was within the normal range for document review in a complex matter." (Dkt. No. 38 Appx016 ¶ 5); *see also* David Degnan, *Accounting for the Costs of Electronic Discovery*, 12 Minn. J.L. Sci. & Tech. 151, 165 (Winter 2011) ("Industry standards suggest that document reviewers can read, understand, and mark 50 documents per hour."). As Mr. Weinfield explains, within these "private practice" reviews, reviewers search for "relevance, responsiveness, privilege, hot documents, confidentiality, attorney-eyes only designation, and coding categories." (Dkt. No. 38 Appx016 ¶ 8). Obviously, just reviewing for PII is far less burdensome than reviewing for all these other categories. Here, not only is the review only for PII

for a majority of the responsive documents but, as shown, most of the documents are also repetitive clinical trial data documents. Thus, this review is not even a "complex" matter requiring a reduced review speed of 50 documents per hour, but rather a simple review that can be accomplished at an even faster rate. Nonetheless, the FDA expects this Court to believe that its reviewers can only review 5 pages per hour.

With just the 11 full time reviewers working 7.5 hours per day and reviewing 50 pages per hour (rather than the absurd claim of just 5 pages per hour), the FDA could review over 88,000 pages per month in February and in March 2022. That is more than sufficient to produce the 55,000 pages per month currently ordered by the Court for these two months, and 8 times greater than the 10,000 per month the FDA requests.

To further confirm these numbers, and the reasonableness of the Court's existing Order, Plaintiff contacted a professional document review company, BIA, is a highly regarded and established document review company that has been performing document review services for law firms for over 17 years. (App000782.) Plaintiff provided BIA with copies of the 8,347 pages of sample CRF data the FDA already produced (after removing redactions and inserting made-up data). BIA estimated it could provide project management, and review and redact those documents for both trade secrets and PII within 50-70 hours, and for a budget of just $3,700. (*Id*.) That is a rate of between 119 and 166 pages per hour.

The FDA could easily retain BIA (or any similar company) for the entire portion of the production that only involves PII. In fact, as noted in Plaintiff's prior papers, BIA estimated it could complete the whole review of all 450,000 pages for PII and trade secrets within 6-8 weeks with 10 reviewers and 1 team lead, for approximately $132,000 (Dkt. No. 31 p. 3), a tiny fraction

of the purported $4 to $5 million the FDA claims it will cost to review these documents (Dkt. No. 37 at 9).

Mr. Weinfield attempts to persuade the Court that the instant FOIA review will be much harder and more time consuming than a typical private practice review. (Dkt. No. 38 at APPX012-19.) In this manner he seeks to defend the indefensible: that the FDA's 11 reviewers can only review around 5 pages per hour. His arguments are irrelevant and/or ridiculous:

- Mr. Weinfield never claims that he has specific knowledge of the documents at issue here. (*Id.* at APPX016 ¶ 3 (attesting that the declaration is merely based on his general "knowledge and expertise in litigation and eDiscovery").) As a result, his conclusions are all just generalizations, and lack any specificity whatsoever, and should therefore be given little if any weight. On the other hand, BIA based its estimation on a sample of the actual documents at issue here.
- Mr. Weinfield does not even try to claim that PII is in any way complicated to identify, and since the majority of the records only require review of PII, his arguments, therefore, have no relevance to the majority of documents at issue. (Dkt. No. 38 at APPX006 ¶ 14 ("By knowing which records the sponsors believe do not contain information protected by FOIA Exemption 4, FDA will be able to … move more quickly through the records if it does not need to search for Exemption 4 material").)
- As for the subset of pages that may contain trade secrets and confidential business information, Mr. Weinfield provides little support for his claim that reviewing for this information here requires more specific knowledge than is required in a private practice review. Take, for example, an antitrust lawsuit involving a Pfizer drug. In

> any event, to the extent that a subset of the responsive documents here could contain trade secrets or confidential business information, the FDA has already involved Pfizer to identify such documents, further undermining any claim of burden. (*See* Dkt No. 38 APPX007 ¶ 15 ("FDA is actively assessing other potential ways in which it may properly enlist Pfizer-BioNTech to assist with streamlining the processing of the records at issue in this suit").) In fact, the FDA has a whole set of regulations specifically addressing how a company submitting documents to the FDA can and should "designate part or all of the information" that it has submitted to the FDA "as exempt from disclosure under exemption 4 of" FOIA, "either at the time the records are submitted to the Government or within a reasonable time thereafter." 21 C.F.R. 20.61(d).

For all these reasons, the FDA's claim that its current 11 full-time reviewers can only review 10,000 pages per month for February and March is simply untrue. On the other hand, if this claim were true, then it raises to a fever pitch questions regarding the competency of the FDA, and it screams the need to get the documents it relied upon to license the Pfizer vaccine into the hands of independent scientists forthwith.

II. The FDA's Delay Tactics Should Not be Countenanced

All Americans must comply with the law. The FDA again asks this Court for special dispensation to avoid what Congress, and this Court, required. Everyday Americans do not get such reprieve. The law is the law. At the current ordered rate, the FDA is already being given leeway with regard to the purpose and intent of FOIA, i.e., timely production. It has been more

than four months since Plaintiff commenced this lawsuit and the documents at issue, to be timely put to good use by independent scientists, are needed forthwith.

That the FDA wants to stall production as long as possible is plain from the fact that during the parties' negotiations and briefing, and during the court hearing, it would not agree to be obligated to produce more than 500 pages per month. The agency made no secret of this goal, even after its counsel was pressed by the Court. And after being ordered to produce at a faster rate, the FDA has no issue with making plainly ludicrous claims to obtain additional delay.

The FDA also makes clear that this latest maneuver will no doubt be only the first in a series of delay tactics. In the FDA's supporting Declaration of Suzann Burk (Dkt. No 38 at APPX002 -APPX013), the agency makes clear its future intentions. First, the FDA is not really asking the Court to produce only 10,000 pages per month for February and March 2022; it is telling the Court it will not comply with the Court's order as it exists today. The FDA explicitly states it may not even meet the dramatically reduced page count of 10,000 pages per month, claiming that even this amount "cannot be guaranteed," rather the agency only states that if the productions were reduced to 10,000 pages for these months, that "would significantly increase the **likelihood** that FDA will be able to comply with the Court's order." (Dkt. No 38 at APPX012 (emphasis added).) Hence, the FDA is saying that it does not intend to comply unless the Court bends to its demand of 10,000 pages for the next two productions and, even then, it may not comply with that amount.

Incredibly, the FDA then goes on to say that it may not comply with the 55,000 pages per month obligation thereafter. Indeed, after claiming the agency will assign 28.5 full time reviewers to the project,[3] the Declaration of Suzann Burk says that:

[3] The FDA is attested to the Court that it plans to hire 15 contractors (Dkt. No. 38 at APPX009 ¶ 22), "detail" 8 agency employees (*Id.* at APPX005 ¶ 8), and assign 5.5 of its normal review staff to the project (*Id.* at ¶ 10), for a total of 28.5 reviewers.

> Even once the new hires fully take effect, meeting the production burden of 55,000 pages per month will pose a challenge to the agency. As discussed above, FDA is making every effort to comply with this Court's order in good faith. But in months where the agency is processing especially challenging records or may be dealing with staff reductions due to illness, attrition, or other reasons beyond FDA's control, the enormity of a 55,000 page per month obligation could still prove too much.

(Dkt. No 38 at APPX008.) In establishing the 55,000 pages per month rate, the Court already took into account "the FDA's concerns regarding the burdens of production" and balanced those against the "need for unprecedented urgency." (Dkt. No. 35 at 3.) As such, the agency cannot simply tell the Court that because of the burden on it, the agency may choose to not comply.

That the FDA does not intent to comply with the Order is further foreshadowed by its harping on its claimed "good faith." It is plainly laying the foundation for not being held in contempt when it later fails to comply with the Order. Judging the FDA by its actions, not its words, it is clear why the FDA filed this motion: it is setting up for delay and more delay later with the cover of supposed good faith attempts at compliance, none of which is actually made in good faith. Thus, should the Court grant the agency its requested inch (a 90,000-page reduction for February and March) in this motion, it has made clear it will subsequently take many miles.

If the FDA is willing to dissemble in this motion by claiming that its current 11 employees assigned to the project can only review on average 5 pages per hour, then there is no reason to think anything it says regarding its intentions are true.

III. Holding the FDA to its Representations, Plaintiff Requests the Monthly Rate Increase to 180,000 Pages Per Month

Since the FDA has affirmed to this Court that it is taking steps to "marshal every possible resource available to it," is "acting with maximal urgency to assemble every possible resource

available to it" and "is putting every available resource at its disposal into its efforts to achieve compliance," the Plaintiff asks that the Court hold the FDA to its representations.

The FDA asserts that over the coming weeks, it will have 28.5 full-time people to conduct a review of the documents. Working 7.5 hours per day for 20 business days in a month, 28.5 people reviewing 50 pages per hour can review a total of approximately 213,750 pages per month.

Reducing this monthly rate by another 15% to allow for different types of documents, and potential delays caused by unforeseen issues – such as "staff reductions due to illness, attrition, or other reasons" referenced by Ms. Burk (Dkt. No 38 at APPX008) – results in an exceedingly reasonable rate of 180,000 pages per month. Meaning, putting aside that a document review company could review these documents within weeks with far less people and for a tiny fraction of the budget claimed by the FDA, and that most of the documents (which only involve PII) can be reviewed far quicker than 50 pages per hour, with 28.5 full time reviewers the agency should be able to easily review 180,000 pages per month.

As for the FDA's claim that the rate in this case is unprecedented, the FDA, as noted in prior argument, fails to identify the relevant metric. The rate is the tail, and the dog is FOIA's requirement that the documents be timely produced. Here, the minimum rate of 55,000 pages per month still means the documents will not be produced until at least the end of September which, given the current issues with the pandemic, is respectfully still not timely for the current needs. Independent scientists need these documents today.

IV. The FDA's Comments Regarding the Cost of the Review or the Need to Reallocate Resources Cannot Serve to Alter the Court's Ruling

The FDA repeatedly makes hyperbolic comments in its papers about the cost of the review and the resources it needs to transfer to comply with the Court's order. However, the FDA never

makes explicit its reasons for making these comments, and it appears the FDA is merely trying to make the Court feel guilty for ordering the production in the first place.[4]

The Court is, other than Congress, the only check on the FDA. In a free country, transparency is paramount, and the FDA has chosen to thwart transparency and the requirements of FOIA by anemically understaffing the office it maintains to respond to FOIA requests. The FDA's understaffing of its FOIA office is in itself a violation of the obligation of FOIA. Decrying that this Court is now making it comply with the law – by making the agency actually produce documents in a timely manner – is incredible. Trying to make the Court feel it is doing something wrong by making the FDA comply with the law is the height of absurdity. That the FDA is not sufficiently staffed to timely respond to all the transparency requests from the American people is not the fault of the Court but rather falls squarely upon the FDA itself for understaffing the personnel available to respond to these requests.

The FDA additionally wants to ensure that the Court's effort to make it come close to complying with the law is a one-time affair for this case and this case only. By the way the FDA describes its supposedly "unprecedented' actions to comply, the agency makes it sound like it is attempting to land a man on the moon, rather than simply produce documents it has in its possession and is statutorily obligated to produce. It is shameful for the agency to continue to

[4] The FDA also attempts to minimize the unprecedented importance that the Court already found regarding the instant FOIA production. In her declaration, Ms. Burk reiterates the FDA's earlier claims that the agency supposedly published information that "provides the public with substantial information that it can use to evaluate FDA's determination approving the" Pfizer vaccine. (Dkt. No. 38 APPX003 ¶ 2.) When it directed that the FDA produce 55,000 pages per month, the Court already dismissed this claim and concluded that the public requires the underlying data so that independent scientists can review the FDA's claims, and not just items created by FDA that were sanitized for public review.

conduct itself in this manner instead of simply doing what it is required to do by statute and now by Court order: timely respond to all FOIA requests.

It is also remarkable for the FDA to claim, with its over $3.41 billion discretionary budget, that compliance here would harm its health policy objectives. Even if the FDA really does need to spend $4 to $5 million, which as shown above is an absurd overestimate, that is an inconsequential amount of its overall discretionary budget. Moreover, the issues with the Pfizer vaccine – including waning immunity, variants evading immunity, the failure to prevent transmission, myocarditis, and pericarditis – show that the FDA's priority should be to address this product before rushing off to engage in other activities.

Instead, the FDA gripes about the fact that it must now purportedly spend $4 to $5 million from its discretionary budget of over $3.41 billion and allocate a few employees when it has over 18,000 of them. The FDA claims the COVID-19 vaccine is the most important thing it is doing to fight COVID-19, yet now when it needs to be transparent with the American public it tries to claim that *every single other* expense it has is more important.

Among the list of its complaints, the agency gripes that it needs to review new product applications and responding to this FOIA at the Court-ordered rate of production adversely affects that. Putting aside that the resources for the instant document review are not material to its 18,000 employees and over $3.41 billion discretionary budget, it fails to advise the Court that pharmaceutical companies pay user fees directly to the FDA in order to carry out these new product application reviews – the user fees are not part of the discretionary budget and amounted to $2.8 billion last year and are expected to exceed that amount this year.[5]

[5] *See* https://www.fda.gov/about-fda/budgets/2021-budget-summary.

If a multi-billion-dollar company's counsel advised the Court that it could not comply with a document demand within even 60 or 90 days for lack of resources, the company would find no safe harbor before almost any federal judge. The FDA shouldn't either.

CONCLUSION

Plaintiff respectfully asks that the FDA's request to reduce the monthly rate for February and March be denied and that, irrespective of whether that request is granted or denied, that the FDA be ordered to produce 180,000 pages on April 30, 2022 and every 30 days thereafter.

Dated: January 24, 2022

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